

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA**

FRESENIUS KABI USA, LLC,

Plaintiff,

and

SANDOZ INC.,

Intervenor,

v.

STATE OF NEBRASKA; THE NEBRASKA
DEPARTMENT OF CORRECTIONAL
SERVICES; and SCOTT FRAKES, in his
Official Capacity as Director of the Nebraska
Department of Correctional Services,

Defendants.

Case No. 4:18-cv-3109

**INTERVENOR SANDOZ INC.'S
BRIEF IN SUPPORT OF MOTION
FOR LEAVE TO INTERVENE**

I. INTRODUCTION

Sandoz is a global leader in generic pharmaceuticals, with the stated mission to discover new ways to improve and extend people's lives. Cisatracurium, a Sandoz product at issue in this case, embodies that mission when used correctly in anesthesia by facilitating endotracheal intubation and providing skeletal muscle relaxation during surgery or mechanical ventilation. Defendants in this action seek to misuse Cisatracurium to achieve the exact opposite purpose: to execute Nebraska Department of Correctional Services (NDCS) inmate Carey Dean Moore by lethal injection. The use of Cisatracurium in this unauthorized manner will cause substantial reputational and other harm to Sandoz, and compromise Sandoz's longstanding efforts to ensure its products are not used for capital punishment.

Cisatracurium is one of four drugs, along with Diazepam, Fentanyl Citrate, and Potassium Chloride, that make up the State of Nebraska's current execution protocol. Fresenius Kabi USA, LLC ("Fresenius Kabi"), which manufactures both Cisatracurium and Potassium Chloride, commenced this action against Defendants on August 7, 2018, alleging various statutory and common law claims and seeking an injunction enjoining Defendants from using Fresenius Kabi's products to perform executions.

The essence of the claims Sandoz seeks to pursue here is in effect no different than that of Fresenius Kabi's claims, except that Sandoz primarily seeks an Order immediately compelling the State of Nebraska to identify the manufacturer of the Cisatracurium to be used in Mr. Moore's lethal injection. Both companies have long-standing, publically-stated opposition to the misuse of their products in capital punishment. They are, therefore, concerned that Defendants' unauthorized and wrongful use of their drugs as part of the State of Nebraska's execution protocol will work a significant and irreparable harm to their reputations and cause substantial injury resulting from, among other things, damage to business and investor relationships and damage to goodwill. Sandoz's claims arise from the same factual basis as Fresenius Kabi's claims, and are based on similar legal issues and theories of liability.

That said, there is no question that Sandoz's unique interests are not adequately represented by Fresenius Kabi. As referenced above, Sandoz's Complaint in Intervention seeks a mandatory injunction that would require Defendants to disclose the manufacturer and distributor of the Cisatracurium that NDCS intends to use. In addition, the injunctive relief requested by Fresenius Kabi will apply only to drugs it manufactures. Thus, even if Fresenius Kabi ultimately prevails, the Court will be unable to grant relief that would prevent Defendants from using Sandoz's Cisatracurium for lethal injection, exposing Sandoz to significant and

irreparable harm should its drugs be used in Mr. Moore's execution. Indeed, media coverage of this matter demonstrates what's at stake. Describing Mr. Moore's upcoming execution, the Washington Post gave voice to critics who charged Nebraska officials with "rushing to carry out an execution cloaked in secrecy with an untested four-drug scheme that carries immeasurable risks for unnecessary pain and a botched execution." Grant Schulte, *Drugmaker Seeks To Block Nebraska from Using Execution Drugs*, ASSOCIATED PRESS, republished by WASH. POST, Aug. 8, 2018.¹ This description stands in stark contrast to Sandoz's fundamental objective to provide therapeutic and life-saving treatments to patients in need.

For these reasons, Sandoz has timely filed the instant motion and is thus entitled to intervention under [Federal Rule of Civil Procedure 24\(a\)](#). The parties will suffer no prejudice as a result of Sandoz's intervention. Discovery has not yet occurred and there is no other basis to deny Sandoz its right to protect its interests in this litigation. Additionally, even if Sandoz was not entitled as a matter of right to intervene, permissive intervention is appropriate under [Federal Rule of Civil Procedure 24\(b\)](#) as Sandoz's claims and Fresenius Kabi's claims share common questions of law and fact. Either way, Sandoz should have the opportunity to protect its interests and ensure that its products are not being misused in an unapproved manner that is anathema to the company's mission.

II. RELEVANT FACTUAL AND PROCEDURAL BACKGROUND

For years Sandoz has been steadfast that it does not support the use of any of its drugs for off-label use in connection with lethal injection. For example, in early 2011 Sandoz took steps to prevent the sale of sodium thiopental in the United States due to the drug's then-

¹ Available at https://www.washingtonpost.com/national/drugmaker-seeks-to-block-nebraska-from-using-execution-drugs/2018/08/08/946b1270-9b16-11e8-a8d8-9b4c13286d6b_story.html?noredirect=on&utm_term=.303a1be1fbf9 (last visited August 2, 2018).

frequent use in lethal injection cocktails and made public statements reaffirming its position that it did not support the sale of its products for the non-approved use of capital punishment. *See* Exhibit A, Sandoz Inc.'s Complaint in Intervention, at Exhibit 4.

In 2013, Sandoz implemented restrictions on the distribution of Rocuronium Bromide to prevent its use in capital punishment, including amending agreements with distributors to prohibit its sale to U.S. prison hospitals. *See* Exhibit A at Exhibit 5. Since then, Sandoz has made clear to its customers, and to the public at large, that its drugs are only to be used to save and sustain the lives of patients for whom they are needed. In 2017, Sandoz implemented restrictions on the distribution of a third drug, Anectine, to prevent its use in capital punishment. *See* Exhibit A at Exhibit 6. Also in 2017, Sandoz reaffirmed its position in an *amicus curiae* brief, which referred to direct communications with Departments of Corrections and government officials in death-penalty states, and described its right to enforce its contractual rights and minimize its exposure to reputational, fiscal, and legal risks associated with the use of its drugs in capital punishment. *See* Exhibit A at Exhibit 7.

In August 2017, Sandoz became aware of a novel execution protocol including Cisatracurium initially proposed by the State of Nevada.² This was the first time any state had included Cisatracurium in a lethal injection protocol, and no state has yet used Cisatracurium in carrying out an execution. Cisatracurium has never been tested or approved for use in lethal injections. The proposed misuse of the drug in executions is therefore experimental and without precedent establishing that it can be administered without causing unconstitutional suffering. Beginning in November 2017 Sandoz began to add distribution restrictions for Cisatracurium to

² Consistent with its long-standing policy, Sandoz moved just days ago to intervene to protect its rights in an action similar to the instant action in Nevada. *See Alvogen v. State of Nevada*, Case No. A-18-777312-B, Sandoz's Mtn. to Intervene (Nev. Dist. Ct. Aug. 3, 2018).

its customer agreements as they came up for renewal that were designed, in large part, to prevent customers from selling Sandoz's Cisatracurium products to state and federal prisons. At that point, Sandoz had no reason to believe that any state had acquired Sandoz-made Cisatracurium for use in executions, and Sandoz was taking active measures to ensure that this would remain the case.

In 2018, Sandoz became aware that the State of Nebraska added Cisatracurium to its execution protocol. Sandoz objected by sending a letter to Defendant Scott Frakes, Governor Pete Ricketts and Attorney General Doug Peterson "to communicate in the clearest possible terms that Sandoz objects to the misuse of Sandoz Cisatracurium [and other drugs] in the administration of capital punishment." *See* Exhibit A at Exhibit 2. Sandoz explained that:

Sandoz's medicines are developed, manufactured and distributed to be used in the healthcare context to further public health. Their use in connection with executions is fundamentally contrary to this purpose

Id. Sandoz was unequivocal that it would not allow the State's use of its Cisatracurium in connection with lethal injection, and demanded the return of its products:

If your state has purchased Sandoz Cisatracurium . . . or any other Sandoz medicines for use in connection with lethal injection executions, we request that you immediately return the Sandoz medicines in exchange for a full refund.

Id. Sandoz did not receive a response.

On August 7, 2018, the same day Fresenius Kabi filed the instant action, Sandoz sent a second letter to Defendant Frakes, Governor Pete Ricketts and Attorney General Doug Peterson requesting that those individuals immediately disclose "whether the Cisatracurium in your inventory and which you intend to use in connection with the execution of Mr. Moore was manufactured by Sandoz" and again objecting to the use of any Sandoz product in Mr. Moore's or any other execution:

If the Cisatracurium is a Sandoz product, Sandoz prohibits the State from utilizing the drug for the purpose of Mr. Moore's execution and requests that it be returned immediately. Sandoz will provide a full refund for the cost of the medication.

See Exhibit A at Exhibit 3. Again, Sandoz did not receive a response.

In light of the State of Nebraska's refusal to provide Sandoz with information about whether it will use Sandoz Cisatracurium for Mr. Moore's execution and proceeding on information and belief that the State in fact intends to use a Sandoz product, Sandoz is entitled to intervene to learn whether NDCS intends to use its Cisatracurium and to protect its commercial interests. Sandoz's products very well could have been obtained by the NDCS for a non-approved purpose in circumvention of Sandoz's longstanding and public objection to the use of its products for capital punishment. As the U.S. Supreme Court has recognized, a manufacturer of a product has the right to not sell its products to certain individuals or entities, and there is a "long recognized right of a trader or manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal." See *United States v. Colgate & Co.*, 250 U.S. 300, 307 (1919); see also *Pacific Bell Tele. Co. v. Linkline Communications, Inc.*, 555 U.S. 438, 448 (2009) (affirming *Colgate*'s continued validity). Absent intervention, Sandoz will not be able to adequately protect this right and will remain exposed to immediate and irreparable reputational harm.

III. ARGUMENT³

A. Sandoz Should Be Permitted to Intervene as a Matter of Right

Federal Rule of Civil Procedure 24(a)(2) entitles an applicant to intervene as of right when the applicant claims an interest in the transaction that is the subject of the action, the disposition of the action may impair the applicant's ability to protect that interest, and the interest is not adequately represented by existing parties to the litigation. Fed. R. Civ. P. 24(a)(2); *see also Chiglo v. City of Preston*, 104 F.3d 185, 187 (8th Cir. 1997). Rule 24(a)(2) provides no fixed deadline for a motion to intervene, but merely requires the motion be "timely." Fed. R. Civ. P. 24(a)(2); *see also SEC v. Flight Transp. Corp.*, 699 F.2d 943, 947 (8th Cir. 1983). A motion to intervene must be construed liberally, "with all doubts resolved in favor of the proposed intervenor." *See Nat'l Parks Conservation Ass'n v. U.S. EPA*, 759 F.3d 969, 975 (8th Cir. 2014). Liberal construction and application of Rule 24 "serves the judicial system's interest in resolving all related controversies in a single action." *Sierra Club v. Robertson*, 960 F.2d 83, 86 (8th Cir. 1992).

1. Sandoz Has a Sufficient Interest in This Litigation's Subject Matter

The first element of Rule 24(a)(2) requires Sandoz to establish a sufficient interest in this litigation's subject matter. In the Eighth Circuit, the sufficient interest test "is primarily a practical guide to disposing of lawsuits by involving as many apparently concerned persons as is

³ The relevant inquiries under Rule 24(a) and 24(b) do not permit the Court to evaluate the merits of Sandoz's Complaint in Intervention. In the course of *granting* motions to intervene, two district courts in the Eighth Circuit have assumed without deciding that futility could be a basis to challenge an intervenor's complaint. Even in those cases, however, the courts likened their respective hypothetical futility inquiries to analyses appropriate under Federal Rules of Civil Procedure 12(b)(6) and 12(c). *See Lange v. Hoskins*, No. 4:12-cv-3148, 2012 U.S. Dist. LEXIS 165541, at *26-27 (D. Neb. Nov. 20, 2012) (evaluating whether claim would survive motion to dismiss); *EEOC v. CRST Van Expedited, Inc.*, No. 07-0095, 2008 U.S. Dist. LEXIS 75354, at *10-11 (N.D. Iowa Sep. 26, 2008) (evaluating whether claim would survive motion for judgment on the pleadings). Accordingly, the Court's August 10, 2018 determination that Fresenius Kabi was unlikely to succeed on the merits of its complaint does not bear on Sandoz's motion to intervene. *See Memorandum & Order* (Doc. No. 38) at 11 (assessing credibility and determining that "[u]nless Director Frakes is lying, it would seem that Plaintiff will have a rough row to hoe on any of the claims asserted in the complaint").

compatible with efficiency and due process.” *Flight Transp. Corp.*, 699 F.2d at 949 (quotation marks omitted). Thus, “[t]he applicant for intervention must have an interest in the subject matter of the litigation, *i.e.*, an interest that is ‘direct,’ as opposed to tangential or collateral.” *United States v. Union Elec. Co.*, 64 F.3d 1152, 1161 (8th Cir. 1995). In addition, “that interest must be ‘recognized,’ *i.e.*, both ‘substantial’ and ‘legally protectable.’” *Id.* (citations omitted).

Sandoz has multiple interests implicated in this action that meet those practical criteria. First, Sandoz has a distinct interest in learning whether NDCS intends to use Sandoz Cisatracurium in Mr. Moore’s execution, as the first count of Sandoz’s Complaint in Intervention requests. That count seeks a mandatory injunction that would require NDCS to disclose the manufacturer and distributor of the Cisatracurium in NDCS’s possession.

Second, if the Cisatracurium in NDCS’s possession was manufactured by Sandoz, Sandoz seeks to assert its right to refuse to do business with those that would misuse its products. In the Eighth Circuit and indeed throughout the country there is a “long recognized right of [a] manufacturer engaged in an entirely private business, freely to exercise his own independent discretion as to parties with whom he will deal; and, of course, he may announce in advance the circumstances under which he will refuse to sell.” *Insulate SB, Inc. v. Advanced Finishing Sys.*, 797 F.3d 538, 545 (8th Cir. 2015) (citing *Colgate*, 250 U.S. at 307). Because the manufacturer of the Cisatracurium at issue is unknown, this litigation very well might relate to Sandoz’s right to decide not to do business with the Nebraska Department of Correctional Services out of fear for the misuse of Sandoz products—a right well within the purview of *Colgate* and its progeny.

Third, Sandoz has an interest in protecting its reputation and goodwill. Sandoz would suffer irreparable harm to its reputation as a company that produces life-enhancing and life-saving drugs if Defendants are allowed to misuse a Sandoz product as part of an execution

process with the exact opposite effect: potentially painful death. Sandoz likely would also suffer cognizable reputational harm even if the Cisatracurium NDCS intends to misuse was produced by a different company because Sandoz would have manufactured and sold a drug that states use in executions.

Further, there is no question that there is a relationship between Sandoz's legally protected interests and the claims at issue. Sandoz, like Fresenius Kabi, seeks injunctive relief to bar the misuse of Cisatracurium in connection with capital punishment, and to prevent the reputational harm that would ensue if the State were permitted to follow through with its intended protocol in Mr. Moore's execution. Accordingly, Sandoz satisfies the first element of the [Rule 24\(a\)](#) analysis.

2. Sandoz Will Not Be Able to Protect Its Interest if It Is Not Permitted to Intervene

Sandoz also can establish that its ability to protect its interest will be impaired if it is not permitted to intervene as a matter of right for at least two reasons. Sandoz's first claim for a mandatory injunction, which seeks to require Defendants to disclose the manufacturer and distributor of the Cisatracurium at issue, is unique to Sandoz's proposed complaint. Fresenius did not include such a request in its Complaint and, impliedly, may not seek to discover whose Cisatracurium NDCS intends to misuse through its execution protocol. Sandoz alone seeks to protect its interest in learning this important information.

For practical reasons, too, Sandoz should be permitted to participate in this case. Absent intervention Sandoz will not be able to engage in the discovery process given the rapid and aggressive nature of this litigation, likely restricting its ability to prosecute any later independent action. A decision in this case permitting the NDCS to use Cisatracurium in an execution could negatively impact Sandoz's and other drug companies' abilities to protect their

business and reputational interests in other cases challenging use of the same drug given the precedent that this case could set. As a result, Sandoz should be granted intervention as a matter of right to protect its unique and important interests in the outcome of this litigation. *See, e.g., CRI, Inc. v. Watson*, 608 F.2d 1137, 1140 & n.2. (8th Cir. 1979) (holding that intervenor “clearly had sufficient interest in the suit and risked sufficient impairment of that interest to intervene as of right,” noting that “[e]ven though [the intervenor] would not have been bound if it were not a party, judgment in [the defendant’s] favor would clearly have been compelling precedent adverse to its own cause of action.”).

3. Sandoz’s Interests Are Not Adequately Represented by Existing Parties

Sandoz should also be permitted to intervene as of right because its interests are not adequately represented by the existing parties in this litigation. The Eighth Circuit has explained that the burden of inadequate representation is “minimal” and requires only that the intervenor’s and the parties’ interest be “disparate,” not necessarily “adverse.” *Planned Parenthood of Minn., Inc. v. Citizens for Cmty. Action*, 558 F.2d 861, 869-70 (8th Cir. 1977) (citing *Trbovich v. United Mine Workers*, 404 U.S. 528, 538 n.10, 30 L. Ed. 2d 686, 92 S. Ct. 630 (1972); *Edmondson v. Nebraska*, 383 F.2d 123, 127 (8th Cir. 1967)).

Even were Fresenius Kabi to prevail on its claims, any permanent injunctive relief would be granted only with respect to Fresenius Kabi’s products. The resolution of Fresenius Kabi’s claims will not have any impact on how the State of Nebraska uses Sandoz’s drugs. Indeed, the State would still be able to use Sandoz’s Cisatracurium to carry out lethal injection over Sandoz’s objections, harming the company’s reputation and business goodwill. Fresenius Kabi has no reason (or standing) to represent Sandoz’s interests in this matter, which weighs heavily in favor of granting intervention.

4. Sandoz's Motion for Intervention is Timely

Finally, Sandoz's motion for intervention is timely. The timeliness of an intervention motion depends on a variety of factors, including how far the litigation has progressed before the motion is filed, the applicant's delay in filing the motion, and the amount of prejudice caused to the other parties if intervention is allowed. See *Mille Lacs Band of Chippewa Indians v. Minnesota*, 989 F.2d 994, 998 (8th Cir. 1993). All of these factors weigh in Sandoz's favor. Only three days have passed since Fresenius Kabi filed this lawsuit; no one can plausibly allege that Sandoz delayed filing this motion; and the parties will not suffer any prejudice from Sandoz joining this suit three days after it was filed.

B. Sandoz Is Alternatively Entitled to Permissive Intervention

Although Sandoz is entitled to intervene as a matter of right, the Court can alternatively grant Sandoz permissive intervention. *Federal Rule of Civil Procedure 24(b)* provides that a party may be permitted to intervene upon timely application when the applicant "has a claim or defense that shares with the main action a common question of law or fact." The Court should consider "whether the intervention will unduly delay or prejudice the adjudication of the original parties' rights." *Id.*

Sandoz's claims here are similar, and indeed intertwined, with those asserted by Fresenius Kabi. The companies' respective claims clearly share a common factual basis and pose nearly identical questions of law. There is no tenable argument that Sandoz's intervention in this action will unduly delay or prejudice the rights of the original parties. Sandoz is not suggesting that any deadlines should be pushed back, or that the litigation should otherwise be delayed to accommodate Sandoz's entry. The litigation began just three days ago. Thus, there are no factors counseling against the Court's use of its discretion to permit Sandoz to intervene pursuant to *Federal Rule of Civil Procedure 24(b)*.

IV. CONCLUSION

Sandoz must be allowed to intervene to protect its legally recognized interests, which are not currently represented by any party. Otherwise, Sandoz will be significantly prejudiced and exposed to significant reputational harm and other injury. For the foregoing reasons, therefore, Sandoz respectfully requests that the Court grant intervention as a matter of right under [Federal Rule of Civil Procedure 24\(a\)](#) or, in the alternative, permit Sandoz to intervene under [Federal Rule of Civil Procedure 24\(b\)](#).

DATED this 11th day of August, 2018.

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CERTIFICATE OF SERVICE

I, Mark A. Christensen, hereby certify that on August 11, 2018, I electronically filed the foregoing Brief in Support of Motion for Leave to Intervene with the Clerk of the United States District Court using the CM/ECF system, which sent notification of such filing to the following:

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